

## **REMARKS**

The Final Office action dated June 17, 2008 is acknowledged. Claims 1-44 are pending in the instant application. According to the Office action, claims 13-24 and 34-44 have been withdrawn and claims 1-12 and 25-33 have been rejected. Claim 1 is amended to incorporate the subject matter of now canceled claim 4. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

### **Rejection of Claims 1-12 and 25-33 under 35 U.S.C. 103(a)**

Claims 1-3, 7-11, 25-27 and 31-33 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,090,403 (Block, et al.). The Examiner maintains the rejection from the previous Office action. In particular, the Examiner states that Block, et al. teach a skin patch for the relief of colds (claim 1), including an underlying layer of non-irritating medical grade pressure-sensitive adhesive, and a foraminous upper carrier layer to which the decongestant-containing ointment is applied (col. 5, lines 4-10). The Examiner further states that the patch is capable of allowing moisture from the skin to diffuse outwardly and escape through the upper surface of the patch (col. 2, lines 52-60). Still further, the Examiner states that the skin patch includes a thickener comprising a natural or synthetic gel-forming polymer selected from the group consisting of gum karaya, carboxymethyl cellulose, polyacrylamide and polyacrylic acid, as well as a humectant comprising a polyhydric alcohol and that the antitussive is camphor or menthol. The Examiner confirms that Block, et al. do not teach the specific claimed amounts of water content of the matrix, hydrophile polymer, essential oil, pressure-sensitive adhesive polymer and adjuvants. The Examiner thus concludes that it

would have been obvious to use the invention of Block, et al. to arrive at the present invention while noting that the specific amounts of the aforementioned items would be obtained by one skilled in the art.

Claims 1-11, 25-29 and 31-33 have been rejected as being unpatentable over the combination of Block, et al. and U.S. Patent Application Publication No. 2003/0167556 (Kelley). The Examiner maintains the rejection from the previous Office action. In particular, the Examiner essentially argues that Block, et al. teach the present invention except for the adsorbent cyclodextrin, emulsifier sodium lauryl sulfate or any claimed amounts of the water content of the matrix, the claimed adsorbent, the emulsifying substance, the detachable protective layer, the hydrophile polymer, essential oil, pressure-sensitive adhesive polymer, adjuvants, emulsifying substance and moisturizers. In addition, the Examiner states that Kelley teaches the missing features of Block, et al. and concludes that it would have been obvious to combine the teachings to arrive at the presently claimed invention.

Claims 1-11 and 25-33 have been rejected as being unpatentable over the combination of Block, et al., Kelley and U.S. Patent No. 5,780,047 (Kamiya, et al.). The Examiner maintains the rejection from the previous Office action. In particular, the Examiner repeats the previous rationale for Block, et al., namely, that it teaches the present invention except for adsorbent cyclodextrin, emulsifier sodium lauryl sulfate or any claimed amounts of the water content of the matrix, the claimed adsorbent, the emulsifying substance, the detachable protective layer, the hydrophile polymer, essential oil, pressure-sensitive adhesive polymer, adjuvants, emulsifying substance and moisturizers. In addition, the Examiner states that Kelley teaches the missing features of

Block, et al. and that Kamiya, et al. teach that the patch is applied on a human skin and exerts medicinal effects on painful stiff neck and shoulder, as well as that the patch may contain essential oils and perfumed oils, such as pine oil. The Examiner concludes that it would have been obvious to combine the teachings of these references to arrive at the presently claimed invention.

Claims 1-12 and 25-33 have been rejected as being unpatentable over the combination of Block, et al., Kelley, Kamiya, et al. and U.S. Patent No. 5,527,536 (Merkle, et al.). The Examiner maintains the rejection from the previous Office action. In particular, the Examiner again repeats the previous rationale for Block, et al., Kelley and Kamiya, et al. In addition, the Examiner argues that Merkle, et al. teach a patch for controlled release of readily available volatile active substances to the skin, where the patch comprises a back layer, and a water-insoluble adhesive film bonded to the back layer, plus a detachable film covering the adhesive film (page 12). The Examiner concludes that it would have been obvious to combine the teachings of these references to arrive at the presently claimed invention.

The Applicants respectfully submit that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitation. The Applicants respectfully submit that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider Block, et al. alone, or in

combination with the cited secondary references, each and every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered.

The Applicants respectfully disagree with the Examiner's conclusion set forth in the Final Office action. It is respectfully submitted that one issue with compositions for medicinal skin patches pursuant to the cited prior art is the insufficient processability thereof since such patches are susceptible to phase separation and rapid increase in viscosity. Therefore, the pot life of such compositions is short and such compositions have to be immediately processed.

For example, when reworking compositions of Block, et al., it was found that a significant increase in viscosity occurs in such preparations within a short time after having been manufactured. The experiments showed that the maximum pot life of the corresponding compositions is only 1 to 2 hours. Thus, further processing of the compositions requires an uninterrupted, continuous production process to even allow the use of such prior art compositions. It has additionally been found that the compositions tend to show phase separation of the oil phase and the hydrophilic basis. This in turn leads to a reduced shelf life and reduced reliability of the product.

It was therefore an object of the presently claimed invention to provide medicinal preparations to enable the release of essential oils for treating colds wherein the aforementioned disadvantages of the prior art, in particular the short pot life of the compositions and phase separation, do not occur.

In the presently claimed invention, it was surprisingly found that by adding substances with an adsorbing effect, pot life can be considerably increased and a

premature phase separation between the oil phase and hydrophilic matrix can be prevented. It has been further shown that a low water content has a positive effect on the pot life of the compositions in accordance with the presently claimed invention. Therefore, the present invention has shown that it is beneficial to manufacture the claimed skin patches to limit the water content in the hydrophilic adhesive for ensuring a long pot life

Moreover, the medicinal skin patch of the present invention enables absorption of a large amount of moisture without losing the structural integrity thereof in the absence of any carrier. This structural integrity not only provides for coherence of the matrix and a continuous release of the active components, i.e., the essential oils, but also provides for sufficient adhesive strength so that the skin patch will not peel off during the required administration time.

Regarding Block, et al., it is respectfully submitted that there is no teaching or suggestion of these positive effects of a low water content of the hydrophilic adhesive matrix, as discussed above. In particular, substances with an adsorbing effect as disclosed in claim 1 are not taught or described in Block, et al. To the contrary, Block, et al. teach that typical hydrophilic ointments explicitly contain water, a humectant and a water dispersible or swellable polymer as a thickener to adjust the viscosity. Therefore, the Applicants respectfully disagree with the Examiner's position outlined in the present Final Office action and the previous Office action, namely, that the low water content of the composition and the addition of adsorbing substances is within the purview of one skilled in the art as a matter of routine optimization since one skilled in the art would have employed such a technique to overcome the aforementioned limitations and

drawbacks of the compositions of Block, et al. The Applicants submit that this is not the case.

The Applicants further disagree with the Examiner's position that the skin patch according to Block, et al. will allow water in the ointment to escape to a minimum amount of remaining water. With hydrophilic substances, this is simply not the case and the substances will release water only under severe conditions. Moreover, in the case of application to the skin, which constantly releases water, the hydrophilic ointment of the skin patch will adsorb water to the saturation limit. Furthermore, as to the Examiner's opinion that an ointment is a viscous semi-solid preparation in which *per se* only a minimum of water is allowed, the Applicants respectfully submit that skin creams and ointment, which fulfill this definition of a semi-solid preparation, typically contain a water content of up to 80% as known in the art. Therefore, an ointment does not necessarily have low water content. In turn, it is submitted that Block, et al. fail to teach or disclose preparations with low water content. Thus, the subject matter of amended claim 1 (and the respective dependent claims) of the present application is clearly not obvious in view of Block, et al.

Regarding the rejection of the claims based on Block, et al. in view of Kelley, the Applicants also respectfully disagree. Kelley fails to make up for any of the aforementioned deficiencies of Block, et al. Kelley pertains to transdermal therapeutic patches for percutaneous administration of anti-aging compounds, whereas the patch has a body formed of a porous material and which comprises an attachment means for connecting the body with the skin.

However, in contrast to the Examiner's position that both Kelley and Block, et al.



teach a patch which is drawn to the same subject matter of the presently claimed invention, it is submitted that the documents pertain to substantially different medicinal fields. In particular, while the patch according to Kelley is designed for transdermal application of an active agent, requiring *inter alia* a transport of agent from backing and matrix to the skin, the patches of Block, et al. and of the present invention employ completely opposite modes of action. As their agents are not effective through the skin, they have to be transported to the outer surface of the backing layer where they are evaporated and subsequently inhaled. Due to this substantially different mechanism, one skilled in the art would not consider the invention of Kelley on the one hand, and the present invention and Block, et al.'s invention on the other hand, as drawn to the same subject matter since inhalation and transdermal administration are two very different routes of drug delivery that can not be compared with each other. Therefore, any skilled artisan who is concerned with realizing administration forms for inhalation therapy in the form of a patch would clearly not have considered the Kelley prior art reference at all.

It is additionally submitted that neither Block, et al. nor Kelley teach the use of adsorbing substances, as set forth in present claim 1, to prolong pot life of the compositions, to prevent phase separation and to stabilize the integrity of the active agent matrix. Even though Kelley teaches the use of cyclodextrins, the cyclodextrins have a completely different function from the present invention. According to Kelley, the cyclodextrins are employed as penetration enhancers to facilitate the absorption of the active agent through the skin. However, in the present invention, as discussed above, the active ingredients are transferred away from the skin and transport through the skin would ultimately result in a loss of the active ingredient.

Thus, the combination of teachings of Block, et al. and Kelley fail to teach or disclose the presently claimed invention.

Moreover, the addition of the teachings of Kamiya, et al. still fail to make up for the deficiencies of the combination of Block, et al. and Kelley. The patches of Kamiya, et al. are water-soluble bathing preparations to which one skilled in the art would refrain from referring since Block, et al. and Kelley teach patches which are applied to the skin for a prolonged time and a high water solubility of the patches would be considered to be an objectionable property for patches of Block, et al. and Kelley. The teachings of Kamiya, et al. fail to suggest or disclose the use of adsorbing substances according to claim 1 to overcome the deficiencies of Block, et al. and Kelley.

The Applicants submit that Merkle, et al. also fail to make up for any of the numerous deficiencies of the aforementioned prior art. Even if one skilled in the art were to refer to Merkle, et al., each and every limitation of the presently claimed invention would not be met.

It is therefore respectfully submitted that the present invention defined in the present claims is patentably distinguishable over the combination of prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences, each and every element of the present invention recited in the present claims are not set forth in the Block, et al., alone or in combination with any of the cited secondary and/or tertiary references. Moreover, one skilled in the art would not be motivated to combine said references or to modify Block, et al. to arrive at the presently claimed invention. Therefore, the Applicants strongly request that this rejection be withdrawn.

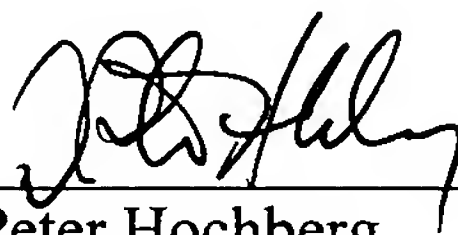
### **Conclusion**



For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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